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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/585,192 | 07/03/2006 | Shigeru Kabayama | 0033-1084PUS1 | 6174 |

2292 7590 10/17/2008

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

| EXAMINER | |
|---|---|
| ARNOLD, ERNST V | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 10/17/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/585,192 | KABAYAMA ET AL. | |
| | Examiner | Art Unit | |
| | ERNST V. ARNOLD | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/08;4/17/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 9-12 and 15 have been cancelled. Claims 1-9, 13 and 14 are under examination. Applicant's amendment has necessitated a new ground of rejection. Accordingly, this action is FINAL.

**Withdrawn rejections:**

Applicant's amendments and arguments filed 6/27/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Cantoro (EP 0698388 A1).

Cantoro discloses artificial salt solutions with a pH of between 6.8 and 7.6 and an osmotic pressure of 140-280 mOsm/L comprising 40 mmol/L sodium, 12 mmol/L potassium and 50 mmol/L chloride (claims 1-12). In the absence of evidence to the contrary, these amounts read on the amounts in instant claims 4-6. While Cantoro does not disclose a hydrogen reactive value of 0.01-1 or the oxidation reduction potential of

between -800 to +200 mV such features are deemed inherent in the composition since all of the components are within the instantly claimed amounts and the fact that the USPTO does not have the analytical equipment necessary to measure physical properties that were previously unmeasured in the art. The burden is the appropriately shifted to Applicant to demonstrate a difference between the prior art and the instantly claimed invention. With respect to the limitation that the ion balance is carried out on electrolytic reduction of water it is the Examiner's position that the prior art product is the same as the instant product in the absence of evidence to the contrary. Please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

With respect to the intended uses of instant claims 9-12, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

**Response to arguments:**

Applicant appears to assert on page 5, paragraph 2 of the remarks that since the cited reference does not disclose an active hydrogen reaction value is 0.01 to 1, then

that is the distinguishing feature of the instant invention. Respectfully, the Examiner cannot agree. The "active hydrogen reaction value" appears to be a made-up in-house value proposed by Applicant (see specification page 8, lines 17-22) and not a commonly used value in the art. The USPTO does not have the analytical equipment necessary to measure physical properties that were previously unmeasured in the art

***Claim Rejections - 35 USC § 102***

Claims 1, 2 and 7-9 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Hoshino et al. (JP2000-157977; IDS filed on 7/3/06).

Hoshino et al. disclose in the English language Abstract an electrolytic water without stimulating or denaturing cells and having high sterilizing power in the electrolytic water generated by electrolyzing a water to be electrolyzed containing, an osmotic pressure regulating substance by specifying the osmotic pressure of the electrolytic water. Hoshino et al. teach how to make the electrolytic water: the electrolytic water is generated by electrolyzing water to be electrolyzed in an electrolytic cell, and the osmotic pressure is set at 128-322 mOsm. At this time, the water to be electrolyzed is the mixed solution of at least one between a chloride such as sodium chloride and a pH regulator such as hydrochloric acid and water. The electrolytic water is preferably kept at a pH of 3-8.5, and the chlorine concentration, of the electrolytic water is preferably controlled to 1-150 ppm. Further, the sodium chloride concentration, is set at 0.4-1.0%. Thus, Hoshino et al. fairly disclose an artificial salt solution with a pH

of 3-8.5 and an osmotic pressure of 128-322 mOsm made by electrolyzing water and anticipating instant claims 1, 2 and 7-9.

While Hoshino et al. do not disclose a hydrogen reactive value of 0.01-1 or the oxidation reduction potential of between -800 to +200 mV such features are deemed inherent in the composition since all of the components are within the instantly claimed amounts and the fact that the USPTO does not have the analytical equipment necessary to measure physical properties that were previously unmeasured in the art. The burden is the appropriately shifted to Applicant to demonstrate a difference between the prior art and the instantly claimed invention.

With respect to the intended uses of instant claim 9, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

**Response to arguments:**

Since the arguments are the same as above, the Examiner's rebuttal is the same as above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 13 and 14 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Morisawa et al. (EP 0826636; IDS filed on 1/28/08) in view of Cantoro (EP 0698388 A1) and Hoshino et al. (JP2000-157977).

Applicant claims an artificial salt solution and a method of making the artificial salt solution.

**Determination of the scope and content of the prior art**

**(MPEP 2141.01)**

Morisawa et al. teaches in claim 9:

**A method of producing electrolytic hydrogen dissolved water comprising the steps of:**

**preparing raw water including at least natrium, kalium, magnesium and calcium ions,**
**obtaining purified water from said raw water,**
**adding a catalyst for promoting electrolysis in said purified water, and**
**electrolyzing said purified water added with said catalyst, and then deriving cathode water.**

Morisawa et al. teach that the catalyst is NaCl (see figure 1). Morisawa et al. teach that the electrolytic water has dissolved hydrogen of at least 0.1 ppm and the solution is *neutralized* which means it has a pH of about 7.0 (claims 1 and 2). The hydrogen reactive value is intrinsic to the composition of Morisawa et al. since it has dissolved hydrogen present. Morisawa et al. teach that the ox-red potential is not more than +100 mV (claim 6). Morisawa et al. teach a wide variety of applications for the solution including transfusion formulation, dialysis treatment solution, peritoneal dialysis solution, or medicine (claim 8).

The references of Cantoro and Hoshino are discussed in detail above and those discussions are hereby incorporated by reference.

**Ascertainment of the difference between the prior art and the claims**

**(MPEP 2141.02)**

1. The difference between the instant application and Morisawa et al. is that Morisawa et al. do not expressly teach the osmotic pressure of the salt solution or the concentration of the sodium, potassium and chloride components. This deficiency in Morisawa et al. is cured by the teachings of Cantoro (EP 0698388 A1) and Hoshino et al. (JP2000-157977).

**Finding of prima facie obviousness**

**Rational and Motivation (MPEP 2142-2143)**

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of Morisawa et al. to produce an

artificial salt solution of 260-2560 mOsm/L or the narrower range of 260-320 mOsm/L with the instantly claimed amounts of potassium, sodium (potassium ion: sodium ions = 1:4 to 1:8) and chloride, as suggested by Cantoro and Hoshino et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Cantoro and Hoshino et al. provide guidance on the proper osmotic pressure to use in biocompatible artificial salt solutions and also provide guidance on the amounts of ions to use in such solutions. It is then merely routine optimization of the amounts of ions taught in the art to use in the method of Morisawa et al. to produce the artificial salt solution at the instantly claimed amounts of potassium ion: sodium ions = 1:4 to 1:8, and physical properties of the resulting solution. The amount of a specific ingredient in a composition, such as the potassium ions and sodium ions, is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. The predictable expected result is a salt solution.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

*Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Response to arguments:**

Applicant asserts that the art does not teach adjusting the content of the sodium ions and potassium ions in a 1:4 to 1:8 ratio. Respectfully, the Examiner cannot agree. Cantoro clearly teaches on page 4, lines 45-53 various concentration of K+ and Na+ that can be used in the invention.

| | | | |
|---|---|---|---|
| $Na^+$ | 40-95 mmol/l | $Cl^-$ | 50-150 mmol/l |
| $K^+$ | 12-28 mmol/l | $HPO_4^{=}$ | 7-20 mmol/l |
| $Ca^{++}$ | 0.4-1.5 mmol/l | citrate | 0.7-2.5 mmol/l |
| $Mg^{++}$ | 0.4-1.0 mmol/l | hyaluronate | 0.05-2% by weight |

One of ordinary skill in the art can easily make a solution with 12 mmol K+ and 48 mmol Na+ for a molar ration of 1:4 and read on the instant invention.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13 and 14 remain/are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,623,615 in view of Morisawa et al. (EP 0826636) and Cantoro and Hoshino et al.

The patent teaches in claim 1:

1. A method of producing electrolytic dissolved hydrogen containing water, comprising the steps of:

providing raw water including at least sodium, potassium, magnesium and calcium ions,

obtaining purified water from said raw water,

adding sodium chloride as an electrolyte to said purified water for promoting electrolysis of said purified water,

electrolyzing said purified water containing said electrolyte, and then deriving cathode water comprising hypochlorous acid from the purified water; and

removing the hypochlorous acid from the cathode water by filtering using active carbon, degassing or distilling.

One of ordinary skill in the art would have readily looked to Morisawa et al. (EP 0826636) and Cantoro and Hoshino (discussed in detail above) to determine the proper hydrogen active value, osmotic pressure, pH and amounts of ions required in the aqueous solution. The amount of a specific ingredient in a composition, such as the potassium ions and sodium ions in a ratio of 1:4 to 1:8, is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention

One of ordinary skill in the art would have recognized the obvious variation of the instant invention over the prior art.

**Response to arguments:**

Applicant's arguments are not persuasive. The art teaches adding sodium ions and potassium ion within the instantly claimed molar ratios as discussed above.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 6:15-3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ernst V Arnold
Examiner, Art Unit 1616

/Mina Haghighatian/
Primary Examiner, Art Unit 1616